REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed June 12, 2008 ("Office Action"). Claims 1–47 pending. Claims 1, 4, 8, 9, 12, 14, 18, 23, 24, 29, 30, 34, 35, 39, and 40 are amended. Claims 44–47 are new. The Advisory Action mailed December 17, 2008 indicated that the Amendment filed November 12, 2008 was not entered. Accordingly, the changes in the attached amendment are shown relative to the claim amendment filed February 6, 2008. Applicant respectfully requests reconsideration and allowance of the pending claims for the following reasons.

Statement of Substance of the Interview

Applicant would like to thank Examiner Fubara for the courtesy of an interview on March 5, 2009. Applicant agrees that the Interview Summary of March 5, 2009 accurately reflects the substance of the interview.

Support for Amended Claims

Support for the new and amended claims, particularly the term "remains a free flowing liquid upon parenteral administration" can be found in the specification, for instance, paragraphs 11, 12, 24, 42, 55, and 56 of the specification[1] as published in U.S. Patent Application Publication No. 2004/0185101 A1. For example, the abstract states that "copolymers are disclosed that . . . are capable of solubilizing drugs . . . in a hydrophilic environment to form a solution at temperatures relevant for parenteral and particularly for intravenous administration benefiting from an aqueous drug solution." Paragraph 11 states "[t]his composition may then be used in preparing a free flowing solution of such drugs suitable for intravenous delivery and also the delivery of drugs by any other route where administration of a drug solution is desired." Paragraph 12 states "[t]he present invention also provides a method for effectively solubilizing a drug, including a hydrophobic drug being solubilized into a hydrophilic environment, and a method for effectively administering such a drug to animals by intravenous (I.V.) delivery." Paragraph 55 further states "the resulting copolymer formed a polymer solution when mixed with an aqueous liquid and remained as a free flowing liquid up to 50°C."

[1] Citation to the specification will be made with reference to the paragraph numbers of U.S. Pub. No. 2004/0185101 A1, which is the Pre-grant Publication corresponding to this application.

Anticipation—35 U.S.C. § 102

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Id.* But "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Manual of Patent Examining Procedure § 2112 IV (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art.). "In relying on a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112 IV (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

The Office Action rejects the claims 1–43 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,004,573 ("Rathi"). Rathi discloses biodegradable low molecular weight triblock poly(lactide-co-glycolide) polyethylene glycol copolymers having reverse thermal gellation properties in aqueous solution at body temperature. Reverse thermal gellation occurs where a composition exists as a liquid at lower temperature, but then forms a gel upon exposure to body temperature. Rathi, col. 4, ll. 56–61. The triblock copolymers of Rathi, thus, exist as liquids at low temperature, but form a gel depot upon parenteral administration (*e.g.*, injection) and exposure to body temperature. These compositions have hydrophobic A-block content up to 83%, and a block copolymer molecular weight between 3100 and 4500 Daltons. Rathi discloses throughout that such compositions possess reverse thermal gellation properties.

The claims require, among other limitations, a biodegradable ABA-type, or BAB-type block copolymer comprising: "50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester . . . wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons . . . and said polymeric composition when formed as an aqueous polymer solution, remains a free flowing liquid upon

parenteral administration." While it was known that block copolymers having predominately hydrophobic content could be used to administer hydrophobic drugs, it was thought that such compositions would have exhibited gelation upon parenteral injection. A person having ordinary skill in the art would, thus, have thought such compositions were useful only for local administration of hydrophobic drugs. It was not expected that predominately hydrophobic block copolymers could remain soluble upon parenteral administration as claimed in this application. As noted in the specification, over a range of hydrophobic A-block from 50.1 to 65% by weight, "it is believed that this desirable solubility characteristic is made possible by maintaining an overall weight average molecular weight of the entire triblock copolymer at between about 1500 and 3099." Specification, ¶ 41.

The Office Action points to various instances where the claimed ranges approach, touch, or overlap, endpoints or points within the broadly disclosed ranges of Rathi. But "the disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points." *Atofina v. Great Lakes Chemical Corp.*, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006). The ranges pointed to by the Examiner are broad and involve numerous factors such as molecular weight, composition of the block copolymer, and concentration of the block copolymer. One would be required to control each of these factors in a manner inconsistent with the purpose of Rathi in order to achieve the claimed invention. In fact, none of the examples disclosed in Rathi include compositions which have the claimed properties. And all the examples of Rathi disclose the opposite effect—formation of a gel upon exposure to body temperature. While Applicant agrees with the Examiner that "[p]roducts of identical chemical composition can not have mutually exclusive properties," the difference between the properties of the claimed compositions and those of Rathi establish that the claimed compositions are novel.

Dependent claims 9, 14, 24, 30, 35, and 40 have been amended to replace the requirement for a functional concentration of 1 to 50% with a requirement that the block copolymer have a concentration that is between about 10 to 30% by weight. These dependent claims now further limit the concentration range of about 5 to 40% set forth in the independent claims. At the concentrations required by the present claims, Rathi's copolymers would have possessed reverse thermal gellation properties. The pending claims have also been amended to require a composition that "remains a free flowing liquid upon parenteral administration." Rathi does not disclose a composition that remains a free flowing liquid upon parenteral administration. Rathi

describes a composition that forms a gel depot upon parenteral administration. Accordingly, the rejection of the pending claim under 35 U.S.C. § 102 as being anticipated by Rathi must be withdrawn.

New claims 44 to 47 include, among other limitations, the requirement of about 52% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester. The data in the specification demonstrates that compositions having about 52% by weight of a biodegradable hydrophobic A polymer block exhibit the solubility enhancing effect over the ranges claimed. As shown in Example 1, the PEG 1000 results in a molecular weight for the block copolymer of 2324 as measured by GPC. The PLGA/PEG ratios in the table, coupled with the PEG Molecular weights of 600, 1000, and 1450 demonstrate that the "solubilizing enhancing function" is present over the molecular weight range of claims 44–47. As discussed above, "a compound and all of its properties are inseparable." Accordingly, claims 44–47 further distinguish Rathi.

Obviousness—35 U.S.C. § 103

An invention is unpatentable under 35 U.S.C. § 103 for obviousness where "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). "The ultimate issue of obviousness turns on four factual determinations: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of nonobviousness." *Merck & Co. v. Teva Pharmaceuticals USA Inc.*, 73 USPQ2d 1641 (Fed. Cir. 2005) (*citing Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) (*quoting In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329 (Fed. Cir. 2006)).

As an alternative to the anticipation ground of rejection discussed above, the Office Action rejects the pending claims under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,004,573 ("Rathi"). The differences between the claimed invention and Rathi are

discussed above. The pending claims now require that the "polymeric composition when formed as an aqueous polymer solution, remains a free flowing liquid upon parenteral administration." In contrast, Rathi is directed solely to compositions that exhibit reverse thermal gellation properties for local administration of hydrophobic drugs. If one were to modify Rathi to meet the claimed invention, then Rathi would no longer be suitable for its intended purpose—local administration of hydrophobic drugs. It is well established that a rationale for obviousness which would render the prior art inoperable for its intended purpose is improper. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) ("Indeed, in the French apparatus were turned upside down, it would be rendered inoperable for its intended purpose. . . . In effect, French teaches away from the board's proposed modification."). Accordingly, the claimed invention is not obvious in view of Rathi and the rejection for obviousness must be withdrawn.

Obviousness—Type Double Patenting

The Office Action rejects claims 1–43 for obviousness-type double patenting over U.S. Patent No. 6,201,072. The claims of U.S. Patent No. 6,201,072 requires a polymer "possessing reverse thermal gellation properties." In contrast, the present claims require a composition that "remains a free flowing liquid upon parenteral administration." There is no overlap between the present claims and those of the '072 patent. Moreover, to the extent that one would modify the claimed invention of Rathi to achieve the presently claimed invention, such modification would render the polymer of Rathi unsuitable for its purpose as reflected in the '072 patent claims (i.e., reverse thermal gellation) which is an improper obviousness rationale. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) ("Indeed, if the French apparatus were turned upside down, it would be rendered inoperable for its intended purpose . . . . In effect, French teaches away from the board's proposed modification."). Likewise, as discussed above, new claims 44–47 further distinguish the compositions disclosed and claimed by Rathi. Accordingly, the rejection of the pending claims for obviousness double patenting over U.S. Patent No. 6,201,072 is improper and must be withdrawn.

CONCLUSION

In the event of any variance between this amount and the fees determined by the U.S. Patent and Trademark Office, please charge or credit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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